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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,150	09/21/2005	Yuko Taniike	071971-0366	7373
53080 7590 07/16/2009 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, NW WASHINGTON, DC 20005-3096				
EXAMINER				
ALEXANDER, LYLE				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
07/16/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,150

Applicant(s)

TANIKKE ET AL.

Examiner

Lyle A. Alexander

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/12/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicants' 11/12/08 amendments and remarks were convincing to overcome the grounds of rejection put forth in the 8/11/08 Office action. However, upon further consideration, a new reference was discovered and will be applied below in the following new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 12 is not clear what structure is intended. It is not clear if the biosensor comprising a single substrate with a sample receiving portion, etc. or a substrate and addition reagent section and moisture absorbing material else where in the sensor. Further, it is not clear how or why the moisture absorbing material changes color. Presumably, the moisture absorbing material contains a colorimetric indicator. Finally, some of the language is awkward, such a "packed in a package."

Clarification could be achieved by using language similar to "A method for measuring an analyte in a sample using a biosensor in a sealed package, said biosensor comprising a substrate that further comprises a sample receiving section, a reagent in a reagent section and a colorimetric moisture absorbing indicating material, the method of using the biosensor comprising: ..." . This claim is also unclear what is intended by " ... is determined to be small ... determined to be large." Small and large

are relative terms and it is not clear how one of ordinary skill in the art could determine what scale is intended.

Claim 14 is not clear how the degree of degradation is determined and what is the distance.

Claim 16 is not clear what is intended by an electron mediator.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Fleming (2008/0118399).

Fleming teaches in paragraph[002] a package of biosensor container reagents for the detection of analytes in biological fluids. Paragraphs[006+] teach various embodiments where a "tab" covers the active area of the biosensor. Paragraph[0046+] teach the reagent include enzymes. Paragraph[0078] teaches the biosensor can also include a colorimetric indicator to determine the moisture content which determines the integrity of the biosensor.

The taught "**biosensor**" has been read on the claimed "*biosensor*", the taught "**tabs**" has been read on the claimed "*packed in a package*", the taught "**reagent**" has been read on the claimed "*reagents*" and the taught "**colorimetric indicator to determine the moisture content**" has been read on the claimed "*moisture absorbing material*". Additionally, Fleming teaching "**removing the tab**" which has been read on

the claimed "*removing the biosensor from said package*" and determining if the moisture content was too high to compromise the sensor.

Response to Arguments

Applicant's arguments with respect to claims 12-21 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander

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Primary Examiner
Art Unit 1797

/Lyle A Alexander/
Primary Examiner, Art Unit 1797